VI. MEDICATION ADMINISTRATION

Module Outline

1. Standards of Public Health Practice
2. Self-Administered Therapy (SAT)
3. Directly Observed Therapy (DOT)
4. Directly Observed Preventive Therapy (DOPT)
5. Practical Aspects of DOT/DOPT
6. Training for Non-medical Providers of DOT/DOPT
7. Counting of DOT/DOPT weeks
8. Non-Adherence
    a. Non-Adherence Indicators
    b. Ways to Detect Non-Adherence
    c. Ways to Improve Non-Adherence

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1. STANDARDS OF PUBLIC HEALTH PRACTICE

VI-1.	Any missed directly observed therapy (DOT) dose is added to the end of the treatment course.
VI-2.	DOT is administered for each patient with suspected or confirmed TB disease throughout the course of treatment.
VI-3.	DOT and directly observed preventive therapy (DOPT) are administered by a trained health care worker (HCW) or other trained designee.
VI-4.	For each patient with TB infection (TBI) <18 years of age or any TBI patient on an intermittent regimen (including weekly INH-RPT combination regimen), treatment is administered by DOPT.
VI-5.	For each patient with suspected or confirmed TB disease, an assessment for adverse effects of medication is conducted prior to administering a dose of DOT/DOPT.
VI-6.	All adverse effects are reported to the TB clinician (physician or nurse practitioner) and documented in patient's medical record.

2. SELF-ADMINISTERED THERAPY (SAT)

Self-administered therapy occurs when the patient ingests doses of prescribed TB disease or TBI medication without the supervision of a trained HCW or other trained designee. SAT is the standard delivery of treatment for most adults with TB infection, with the exception of certain individuals (**Refer to DOPT below**).

Persons with suspected or confirmed TB disease receiving DOT therapy, and persons <18 years of age with TBI receiving DOPT may self-administer **only** when discussed with and approved by

the TB physician. If the patient is allowed to self-administer medications, leave only enough medication with the patient for the specified day(s) of self-administration. Inform the patient that all self-administered doses will be added on to the end of the treatment course. For persons with suspected or confirmed TB disease, SAT is not permitted during the first 14 days of therapy and is not recommended during the Initial Phase.

3. DIRECTLY OBSERVED THERAPY (DOT)

Directly observed therapy (DOT) is the direct visual observation by a trained individual of a patient's ingestion of TB medicines. In Tennessee, DOT is the standard of care for treatment for:

1. Persons with suspected or confirmed TB disease (**Standard of Public Health Practice VI-2**)
2. Persons with TB treatment failure or relapse
3. Persons with a history of treatment for TB disease or TBI
4. Persons receiving the 12-week regimen of Isoniazid-Rifapentine (3HP)

Daily or intermittent therapy is administered by DOT for each patient with suspected or confirmed TB disease (**Standard of Public Health Practice V-4**).

Any missed DOT dose is added to the end of the treatment course (**Standard of Public Health Practice VI-1**).

The frequency of DOT for patients with suspected or confirmed TB disease is:

- **Daily**
    - Daily DOT (seven (7) out of seven (7) days) during the initial two (2) weeks of therapy, including the weekends and holidays.
    - Daily DOT needs to be given as long as the patient is on respiratory isolation, even if it extends beyond two (2) weeks.
        - If the patient is housed in a motel, DOT must be provided daily, including the weekends and holidays, as long as patient remains in the motel on respiratory isolation.
        - If respiratory isolation is discontinued after the initial two (2) weeks of therapy, the frequency DOT can be changed with a written order from the TB physician.
    - After the initial two (2) weeks (or more, if isolation is prolonged), DOT can be administered five (5) out of seven (7) days a week, as ordered by the TB physician. The patient can either skip the weekend doses or self-administer for two (2) days (unless the TB physician orders DOT to be continued over additional weekends and holidays).
    - The five (5) doses must be given in a Sunday-Saturday period to be counted as a full week of DOT.

- If a daily Monday-Friday dose is missed, it must be given on Saturday by DOT if practical for TB program staff, otherwise, it must be added to the end of the treatment course.
- Patients **should not** be allowed to self-administer more than two (2) out of seven (7) daily doses, including holidays/weekends. Special permission must be obtained from and documented by the TB physician to allow patients to self-administer medications for more than two (2) days (i.e., during travel). During this time period, the patient must be changed to daily therapy.

- **Intermittent**
  - **Twice weekly:** If ordered 2x (times) per week, both doses must be given by DOT with at least 72 hours between each dose (Sunday through Saturday).
  - **Thrice weekly:** If ordered 3x per week, all 3 doses must be given by DOT with at least 48 hours between each dose (Sunday through Saturday).
  - **Once-weekly:** If ordered 1x per week, each dose must be given by DOT with at least 5 days between each dose (Sunday through Saturday).

Persons with suspected or confirmed TB disease with a known HIV-positive status or an **unknown HIV status** should **not** be placed on any once weekly or twice weekly regimen for TB disease or TBI.

If the patient is on intermittent therapy and plans to travel:

- An order should be written by the TB physician to change the medication to daily dosing for self-administration during this period;
- All self-administered doses will be added to the end of the treatment course; and
- Patient must receive the correct total number of DOT doses and counted weeks of therapy within the specified timeframe prior to consideration for treatment completion.
- If the patient plans to stay an extended time period in another state, arrangement should be made for that state to DOT and an interjurisdictional form will have to be sent to the TTBEP C.O. to be sent to the other state **(Refer to Module VIII: Intra- and Interstate Transfers)**.

4. DIRECTLY OBSERVED PREVENTIVE THERAPY (DOPT)

Directly observed preventive therapy (DOPT) is the direct visual observation by a trained individual of a patient's ingestion of TBI medicines. DOPT will be provided for all children **<18** years of age (**Standard of Public Health Practice VI-4**), and adults receiving TBI treatment that meet the following criteria for DOPT:

- HIV-positive and other immunosuppression
- Persons unable to reliably self-administer medications
- Persons with a known history of substance abuse (including alcohol and drugs)
- Contacts to multidrug-resistant TB (MDR-TB) patients
- Persons who are non-adherent
- Contacts with recent TST or IGRA conversion
- Persons receiving intermittent therapy

The frequency of intermittent DOT/DOPT for **TBI** (**Standard of Public Health Practice VI-4**) is:

- Isoniazid (INH) can be given by DOPT two (2) times per week, with at least 72 hours between doses
- Rifampin (RIF) can only be given daily
- Isoniazid (INH) plus rifapentine (RPT) (aka the "3HP" regimen) is given one (1) time per week by DOPT, with at least five (5) days between doses

5. PRACTICAL ASPECTS OF DOT/DOPT

DOT and DOPT allow for early identification of non-adherence, early recognition of adverse drug reactions and signs of clinical worsening of TB disease.

- DOT/DOPT is administered by a trained health care worker (HCW) or other trained designee (**Standard of Public Health Practice VI-3**)
- DOT/DOPT can be provided at any site that is mutually agreeable to the patient and public health staff, and allows for staff safety, patient comfort, and confidentiality (e.g., office, clinic, patient's home, place of employment, school, street corner, restaurant, etc.)
- Ensure the physician's medication orders are documented in the chart, including the drug name, dosage, frequency, etc.
- Medications should not be left with the patient, a family member, or other person to be taken later. Exceptions include:
    - If the TB physician has ordered the patient to self-administer the medications over a weekend or holiday. In this situation, only enough packets of medications should be left with the patient for that time period.
    - If a packet of TB medications has been left in the home for the patient to take during inclement weather, DOT staff should call and instruct the patient to take the medication due to inability to perform DOT due to the adverse weather.
- Medications should not be left at the home or other meeting place if the patient is not there when the DOT/DOPT visit is attempted.
- Assess the patient for current signs and symptoms of TB disease or side effects of the medication and ask the patient about signs and symptoms or side effects since the last dose of medication before administering the next dose (**Standard of Public Health Practice VI-5**).
- All adverse effects are reported to the TB clinician (physician or nurse practitioner) and documented in the patient's medical record (**Standard of Public Health Practice VI-6**).
- DOT/DOPT involves more than the delivery of medication and witnessing the patient taking the medication:
    - Face the patient and observe him/her swallow each dose. Ask the patient to open his/her mouth and show that the pill has been swallowed. This should preferably be done one pill at a time. Patients can take several pills at once if they prefer, but be sure that all pills are swallowed.
    - Obtain a drink to wash down the pills prior to giving the pills to the patient.

- In settings where more than one person is on DOT/DOPT (i.e., families where more than one member is being treated), administer therapy to one patient at a time.
- Ideally, the same person should administer DOT/DOPT to a patient throughout therapy. If this is not feasible, then all staff responsible for DOT/DOPT should agree upon a standard method of DOT/DOPT to ensure consistency for that patient (i.e., if the patient prefers to take one pill at a time, all staff should offer the pills one at a time).
- Try to tailor the DOT/DOPT to each patient's needs by arranging DOT/DOPT around the patient's work schedule. Altered work hours for the HCW will need to be arranged by the health department.
- Confirm arrangements (date, time and location) for the next DOT/DOPT dose.

6. TRAINING OF NON-MEDICAL PROVIDERS OF DOT/DOPT

The health department bears ultimate responsibility for DOT/DOPT; however, other persons can be trained by the health department to share this responsibility. Medical persons are preferred (they can provide clinical monitoring as well), but non-medical persons can be trained to provide DOT/DOPT. Per the current Community Health Services (CHS) policy, a Public Health Representative/Disease Intervention Specialist may issue packaged and labeled TB oral medications in the field with the approval of the Regional Medical Director and Regional Nursing Director. **Refer to current Community Health Services (CHS) policy for the criteria that must be met prior to delegation of this responsibility**.

Other responsible DOT/DOPT providers may be:

- School nurses,
- Employee health nurses, and
- Clergy

All DOT/DOPT providers will be educated and trained to:

- Visually and verbally identify medication(s).
- Explain medication dosage and adverse effects to the patient.
- Know the adverse effects that may develop from each medication (i.e., nausea, inability to eat, vomiting, abdominal pain, rash, tea-colored urine, yellowing of skin or of the white part of the eyes, or joint pain).
- Instruct patient to hold medication if adverse effects are present, to notify the TB case manager, and to relay the patient's complaints to the TB physician. All instructions and reports must be documented in the patient's medical record.
- Remain with the patient for at least 20 minutes after DOT/DOPT dose is given to ensure digestion of the medication.

If a trained individual other than a health department employee will perform DOT/DOPT, the patient must sign a release of information (ROI) to ensure HIPAA compliance.

For patients residing in congregate/institutional settings that are conducive to observation of therapy, staff employed by that facility can be trained to provide DOT/DOPT according to health department standards. Other facilities may include:

- Hospitals,
- Nursing homes,
- Correctional facilities, and/or
- Methadone or other alcohol and drug treatment sites.

DOT/DOPT should never be given by:

- Family members
- Friends

If an individual other than a health department employee is administering DOT at request of the health department, the TB case manager will:

- Follow-up with the provider at a minimum of monthly to ensure DOT is occurring;
- Ensure the patient has no complaints of side effects to medications;
- Verify if other issues have developed that may hinder treatment compliance; and
- If any adverse effects or other health problems are reported, obtain DOT record and schedule patient in TB clinic to be re-evaluated by the TB clinician.

Reference:

1. Current TB Nursing Protocol

7. COUNTING DOT WEEKS

Completion of treatment is determined by the total number of doses taken and the duration of therapy, indicated by the weeks of treatment completed. The definition of a "DOT week" according to the Centers for Disease Control and Prevention (CDC) and TTBEP is Sunday-Saturday (Sun-Sat).

Document all medication given in the patient's medical record utilizing the current medication administration record (MAR) for the region/metro. An explanation should be documented for all missed DOT doses.

To calculate **Number of weeks of DOT**, use the following methods:

- Review the patient's medication records to determine the number of doses given by DOT each week, or seven (7) -day period (Sun-Sat). Self-administered doses are not counted as part of the week of treatment.
- If a patient misses a DOT dose or there is a holiday during a medication week (i.e., DOT cannot be given that week), as long as DOT is used when the missed dose(s) is made up at the end of therapy, the dose(s) given at the end of therapy can be combined with the last "partial DOT week" and counted as a "full DOT week."

- Count as a DOT week any week during which DOT was used for every dose for a patient who was taking medication one to five (1-5) times a week. If the patient was taking medication seven (7) times a week, DOT must have been used for at least five (5) doses.
- Number of weeks of DOT is based on the total number of regimen-appropriate weeks and doses ingested under DOT.

When counting the calendar week, remember the following:

- **Daily:** Count week only if five **(5)** or more doses were given by DOT (Sun-Sat)
- **Twice weekly:** Count week only if **both** doses were given by DOT (Sun-Sat)
  - Must be at least 72 hours between twice weekly doses
- **Thrice weekly:** Count week only if all three **(3)** doses were given by DOT (Sun-Sat)
  - Must be at least 48 hours between thrice weekly doses
- **Once-weekly:** Count week only if **dose** given by DOT (Sun-Sat)
  - If using INH/RPT (3HP), there must be at least five (5) days between doses

NOTE: If patient does not receive the above number of DOT doses, **do not count the week!**

Determine how many weeks should be included:

- 4-month regimens require 18 weeks
- 6-month regimens require 26 weeks
- 9-month regimens require 39 weeks
- 12-month regimens require 52 weeks

Please discuss with one of the TTBEP C.O. public health nurse consultants if assistance is needed in counting partial weeks/doses of DOT for determination of treatment completion.

Reference:

1. CDC. Report of Verified Case of Tuberculosis: Self-Study Modules. 2009. http://www.cdc.gov/tb/programs/rvct/InstructionManual.pdf (adapted).

8. NON-ADHERENCE

Patient non-adherence is the primary reason for treatment failures and relapses and may occur in patients of all ages.

Non-Adherence Indicators

Table VI-2 identifies non-adherence indicators.

Table VI-2: Non-Adherence Indicators

• Patient will not accept that he/she has TB and will not accept that it can harm him/her	• Patient has undue concern about possible side effects of the TB medication
• Patient has extreme fears or misconceptions about TB, the health department, etc.	• Parent indicates concern about child on TB drugs who has difficulty taking medicine or the parent refuses medication for the child
• Patient complains about the clinic or staff	• Patient seems confused about medication
• Patient indicates that the health care worker does not trust him/her	• Patient does not keep appointments after being reminded
• Patient abuses drugs or alcohol	• Patient is homeless
• Patient is late for the first two (2) appointments	• Sputum smear or culture doesn't convert within two (2) months, or the patient fails to send in sputum specimens
• Chest X-ray does not improve	• Patient has a history of non-adherence to treatment of TBI or other medical conditions
• Communication barriers exist	• Cultural or religious barriers to treatment exist

How to Detect Non-Adherence

Table VI-3 identifies ways to detect non-adherence.

Table VI-3: Ways to Detect Non-Adherence

• Identify patients who fail to keep appointments	• Conduct a pill count at home or clinic visit
• Ask in a non-threatening manner if patient is taking medication	• Identify patients with a prior history of non-adherence
• Use tests (i.e., therapeutic drug monitoring) to measure levels of tuberculosis drugs for patients suspected of being non-adherent	• Identify patients who have not converted their sputum smear or culture to negative within the expected timeframe
• Evaluate urine sample for orange discoloration if taking rifampin	

Table VI-4 identifies ways to improve adherence.

Table VI-4: Ways to Improve Adherence

• Directly observed therapy (DOT)	• Improve staff-patient rapport, especially communications, written instructions and patient education
• Promptly contact patients who miss appointments and assist the patient in solving problems affecting adherence (providing transportation, reminding of appointment)	• Tailor the taking of TB medications with the patient's daily habits (e.g., having morning coffee or meals, including the use of reminders)
• Simplify the treatment as much as possible. Use combination drugs (Rifamate®, Rifater®) and intermittent treatment (2-3 times per week)	• Negotiate with the patient regarding clinic appointments, medication schedule, etc.
• Educate and engage other friends or family members who can encourage adherence (avoid persons that are a negative influence)	• Provide clear verbal and written instructions for taking medication in patient's preferred language
• Provide information to patients about therapeutic response to treatment and test results	• Encourage and praise patient when possible
• Provide closer supervision including home visits for counseling, monitoring, collection of sputum and lab specimens, and DOT	• Do not take an "either/or" position with patients, especially with alcohol users
• Tell the patient the drugs cannot be used for other illnesses. Some patients will save expensive medicine for another illness	• If possible, prevent long waits to see physician
• Send patients appropriate holiday, birthday, and get well cards when hospitalized	• Have patient see physician frequently
• Fear-arousing health messages including isolation and confinement of patients for failure to comply should be reserved until all other strategies have failed	• Offer incentives and enablers to improve adherence